

### REMARKS

Claims 17, 19-23, and 25-37 are pending.

In the Office Action mailed April 1, 2008, claims 17, 19-23, 25-28, and 35-37 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 4,292,324 to Johnson et al. ("*Jonhson*"). Claim 29 has been rejected as allegedly anticipated by U.S. Patent No. 3,901,967 to Cohen et al. ("Cohen"). Claim 30 had been rejected as allegedly anticipated by U.S. Patent No. 4,987,127 to Sirany ("*Sirany*"). Claim 31 has been rejected as allegedly anticipated by U.S. Patent No. 3,134,718 to Nobile ("*Nobile*"). Claim 32 has been rejected as allegedly anticipated by U.S. Patent No. 4,839,341 to Massey ("*Massey*"). Claim 33 has been rejected as allegedly anticipated by U.S. Patent No. 4,292,342 to Jonsson et al. ("*Jonsson*"). Claim 34 has been rejected as allegedly anticipated by U.S. Patent No. 3,032,584 to John ("*John*"). Claims 35-37 have been rejected as allegedly indefinite under 35 U.S.C. § 112, second paragraph.

Applicants make reference to Amendment filed on August 1<sup>st</sup>, 2008 and respectfully request the Examiner to consider the present paper further to the August 1<sup>st</sup>, 2008 paper. In the claim section, the claims have been marked in reference to the August 1<sup>st</sup> Amendment. With respect to argument, Applicants respectfully request the Examiner to consider the present paper instead of the August 1<sup>st</sup> paper.

By this Amendment, Applicants amended claims 17, 19-21, 23, 25-27, 29-34, cancelled claims 28 and 35-37, and added new claims 38-48. Applicants respectfully request reconsideration and allowance of all pending claims in view of the amendments and remarks set forth below.

#### I. CLAIMS TO BIPATHIC MEDICATION ARE NEITHER ANTICIPATED NOR OBVIOUS

As amended, claim 23 now recites (in clean form):

23. A bipathic medication; comprising a pharmaceutically active combination of
- i) a therapeutic dose of an active medicinal substance; and

ii) a homeopathic dilution of said active medicinal substance;  
said active medicinal substance and said homeopathic dilution being admixed or incorporated with one another;  
wherein said pharmaceutically-active combination possesses enhanced therapeutic properties in comparison with said active medicinal substance alone, said enhanced therapeutic properties being enhanced therapeutic effectiveness or reduced side effects.

As explained in the specification, the underlying invention is based on the discovery that a treatment of a pharmaceutically active compound with a homeopathic dilution of the compound fundamentally modifies the properties of the compound itself. The file wrapper of the present patent application clearly demonstrates this discovery and supports it.

The Examiner cited numerous prior art references that disclose pharmaceutically active compounds at normal therapeutic doses. None of the references discloses, teaches or suggests the discovery claimed in the present patent application. In this regard, the Examiner appears to suggest that the bipathic combination is nothing more than a combination of large dose and a small dose of the same molecule, resulting in a mixture of components with same chemical identity. On this ground, the Examiner appears to suggest that the prior art references inherently disclose the claimed invention.

Applicants strongly and respectfully disagree.

A. The Cited Prior Art Does Not Anticipate Claim 23 and Dependent Claims

To anticipate a claim, a reference must disclose either explicitly or inherently, each element of the claim “as set forth in the claim.” MPEP §2131, *citing, Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

It is abundantly clear that none of the references cited by the Examiner discloses the invention of claim 23, either explicitly or inherently.

First, evidence in the file wrapper shows that, contrary to the Examiner’s assertion, the properties of the composition of the prior art is not identical to the claimed composition. As set forth in the MPEP, “[p]roducts of identical chemical composition cannot have mutually exclusive properties.” MPEP §2112.01, *citing, In re Spada*, 15

USPQ2d 1655, 1658 (Fed. Cir. 1990). The evidence in the file wrapper makes clear that the properties of a pharmaceutically active compound before and after treatment with a homeopathic dilution do differ. For this reason alone, the cited prior art cannot anticipate amended claim 23.

Second, none of the references cited by the Examiner discloses a therapeutically active compound that “*possesses enhanced therapeutic properties in comparison with said active medicinal substance alone, said enhanced therapeutic properties being enhanced therapeutic effectiveness or reduced side effects,*” as recited in amended claim 23. It is undisputed that the prior art does not contain explicit disclosure of this limitation of claim 23. Thus, the Examiner appears to rely on inherency to establish a *prima facie* case of anticipation.

Inherent anticipation requires a showing that, while not disclosed explicitly, the prior art composition does possess the properties of the claimed invention. MPEP §2112. Further, to establish a *prima facie* case of inherent anticipation, the Examiner must show scientific rationale or objective evidence tending to show inherency. *See id.* The evidence in the file wrapper is directly to the contrary.

Applicants respectfully direct the Examiner’s attention to the Declaration of Dr. Oleg Epstein (“the *Epstein Declaration*”) filed with the paper of February 8, 2008, which includes data for bipathic combinations based on ethanol, morphine, cyclophosphane, prednizolon, and phenazepam. The data in the *Epstein Declaration* establish the viability of the bipathy phenomena across different types of therapeutic compounds. Furthermore, Applicants note that claim 23, as amended, recite only those bipathic combinations that possess the claimed properties. Quite simply, the prior art cannot include compositions with recited properties since the prior art does not disclose treatment with homeopathic dilution. For these reasons, the scope of showing in the *Epstein Declaration* is commensurate with the scope of the claims.

Applicants respectfully assert that claim 23 and dependent claims are not anticipated by the cited references. Withdrawal of the rejection is respectfully requested.

B. The Cited Prior Art Does Not Render Claim 23 and Dependent Claims Obvious

To set forth a *prima facie* case of obviousness over a reference, the Examiner must show that the reference provides one skilled in the art with the reason to modify the teachings of the reference in the direction of claimed invention as a whole. MPEP §2141.02. “From the standpoint of patent law, the compounds and its properties are inseparable.” *See id.*, citing, *In re Papesh*, 137 USPQ 43, 51 (CCPA 1963). It is clear that “obviousness cannot be predicated on what is not known at the time the invention is made, even if the inherency of a certain feature is later established.” *See id.*, citing, *In re Rijckaert*, 28 USPQ2d 1955 (Fed. Cir. 1993). The treatment of pharmaceutically active compounds with homeopathic dilution to enhance its therapeutic effectiveness was, without doubt, unknown prior to the filing of the present patent application. Quite simply, nothing in the prior art directed an artisan to do so.

Applicants respectfully assert that claim 23 and dependent claims are not obvious over the cited references. Withdrawal of the rejection is respectfully requested.

## II. CLAIMS TO A METHOD OF USING A BIPATHIC MEDICATION ARE NEITHER ANTICIPATED NOR OBVIOUS

Applicants respectfully direct the Examiner’s attention to new claims 46-48, which are directed to a method of treating a disease or condition using a bipathic medication of claim 23. These claims replace cancelled claims 35-36.

New claims 46-48 depend from claim 23. Therefore, all arguments made with respect to amended claim 23 are fully applicable herein.

Furthermore, applicants respectfully direct the Examiner’s attention to data in the *Epstein Declaration* that show enhanced therapeutic effectiveness of the bipathic medication in comparison with the same active compound alone. These data clearly carry additional weight with respect to claims 46-48.

Allowance of new claims 46-48 is respectfully requested.

## III. CLAIMS TO A METHOD OF MAKING A BIPATHIC MEDICATION ARE NEITHER ANTICIPATED NOR OBVIOUS

As amended, claim 17 now recites (in clean form):

17. A method of making a bipathic medication, comprising the steps of:
  - providing an active medicinal substance in a therapeutic dose;

providing a homeopathic dilution of said active medicinal substance; and  
admixing or incorporating said therapeutic dose and said homeopathic dilution with one another thus producing said bipathic medication.

None of the references cited by the Examiner disclose a homeopathic dilution, let alone mixing a homeopathic dilution with a therapeutic dose of active medicinal substance. Applicants respectfully assert that the cited prior art neither anticipates nor renders obvious claim 17 and dependent claims. Withdrawal of the rejection is respectfully request.

#### IV. REJECTION OF CLAIMS 35-37

The Examiner rejected claims 35-37 as indefinite for not setting forth “what is being treated.” Applicants cancelled claims 35-37 and replaced them with new claims 46-48. New claims clearly describe the subject of treatment. Therefore, the rejection has been obviated.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 11-0223.

Respectfully submitted,

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